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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	6

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/445,223	Applicant(s) Wallach et al
	Examiner Minh-Tam Davis	Group Art Unit 1642

X Responsive to communication(s) filed on *Jul 19, 2000*.

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-39* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

X Claims *1-39* are subject to restriction or election requirement.

Application Papers

X See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

X Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 11, 23, ~~25~~ 24-26, drawn to a DNA sequence encoding B1 protein, isoforms, fragments or analogs thereof, a vector, and a host cell transformed with said vector, an anti-sense sequence, and a method for producing B1 protein, fragments or analogs thereof.

Group II, claim(s) 9-10, 22, ~~25~~ 24-26, and 38, drawn to B1 protein, isoforms, fragments or analogs thereof.

Group III, claim(s) 12, drawn antibodies specific for B1 protein, isoforms, fragments or analogs thereof.

Group IV, claim(s) 13, 21, 29-30, 39, drawn to a method for modulation in cells the activity of inflammation or cell death or cell survival pathways, or any other signaling activity, comprising introducing into said cells one or more B1 protein, isoforms, fragments or analogs thereof.

Group V, claim(s) 13-15, 21, 29-30, 39, drawn to a method for modulation in cells the activity of inflammation or cell death or cell survival pathways, or any other signaling activity, comprising introducing into said cells a DNA sequence encoding B1 protein, isoforms, fragments or analogs thereof.

Group VI, claim(s) 16, drawn to a method for modulation in cells the activity of inflammation or cell death or cell survival pathways, or any other signaling activity, comprising treating said cells with antibodies specific for B1 protein, isoforms, fragments or analogs thereof.

Group VII, claim(s) 17-18, drawn to a method for modulation in cells the activity of inflammation or cell death or cell survival pathways, or any other signaling activity, comprising treating said cells with antisense sequence for at least part of the DNA sequence encoding B1 protein, isoforms, fragments or analogs thereof.

Group VIII, claim(s) 19, drawn to a method for modulation in cells the activity of inflammation or cell death or cell survival pathways, or any other signaling activity, comprising treating said cells with a ribozyme.

Group IX, claim(s) 20, drawn to a method for identifying B1 protein, comprising applying the yeast two-hybrid procedure.

Group X, claim(s) 23, drawn to a vector encoding a protein capable of binding a cell surface receptor and encoding at least one B1 protein.

Group XI, claim(s) 25-26, drawn to a molecule capable of disrupting the direct interaction of B1 protein with one or more molecules to which a B1 protein binds.

Group XII , claim(s) 25-26, drawn to a molecule capable of disrupting the indirect interaction of B1 protein with one or more molecules to which a B1 protein binds.

Group XIII, claim(s) 27, drawn to a molecule capable of interfering with the protein kinase activity of B1.

Group XIV, claim(s) 28, drawn to a method for preventing or treating a pathological condition, comprising administering B1 protein, isoforms, fragments or analogs thereof.

Group XV, claim(s) 28, drawn to a method for preventing or treating a pathological condition, comprising administering a DNA molecule encoding B1 protein, isoforms, fragments or analogs thereof..

Group XVI, claim(s) 28, drawn to a method for preventing or treating a pathological condition, comprising administering a molecule capable of disrupting the direct interaction of B1 protein, isoforms, fragments or analogs thereof with one or more molecules to which B1 protein, isoforms, fragments or analogs thereof binds directly.

Group XVII , claim(s) 28, drawn to a method for preventing or treating a pathological condition, comprising administering a molecule capable of disrupting the indirect interaction of B1 protein, isoforms, fragments or analogs thereof with one or more molecules to which B1 protein, isoforms, fragments or analogs thereof binds indirectly.

Group XVIII, claim(s) 31, 33-37, drawn to a method for screening or identifying and producing a ligand for B1.

Group XIX, claim(s) 32, drawn to a method for screening a DNA sequence encoding a ligand for B1.

Group XX, claim(s) 36-37, drawn to a method for identifying and producing a molecule capable of indirectly modulating the cellular activity modulated/mediated by B1.

In addition, upon the election of any of groups I-XX, further election of the following patentably distinct species of the claimed invention is required:

1) B1 protein, fragments thereof, or 2) isoforms, analogs or derivatives of B1.

Upon the election of any of groups IV-VIII, further election of the following patentably distinct species of the claimed invention is required:

1) Inflammation or 2) cell death or cell survival pathways, or 3) other signaling activity.

Upon the election of group VI, further election of the following patentably distinct species of the claimed invention is required:

1) Extracellular application, or 2) intracellular application.

Upon the election of any of groups IX, XIX, further election of the following patentably distinct species of the claimed invention is required:

CARD, kinase or intermediate domains.

Upon the election of any of groups XIV-XVII, further election of the following patentably distinct species of the claimed invention is required:

1) Preventing a pathological condition or 2) treating a pathological condition.

Upon the election of group XVIII, further election of the following patentably distinct species of the claimed invention is required:

1) Whole length B1, 2) carboxy terminal portion of B1, or 3) N-terminal portion of B1.

2. The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international stage application shall relate to one invention only or to a group of invention so linked as to form a single general inventive concept. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475 (d)).

Group I, drawn to a DNA sequence encoding B1 protein, and a method of use of said DNA sequence, forms a single inventive concept.

Groups II, III, X-XIII are additional products. The protein and antibodies of group II and III, respectively, are structurally distinct from the DNA molecule of group I. Further, the vector sequence of group X is distinct from the DNA molecule of group I, because they are structurally distinct. The molecules of groups XI-XIII are structurally distinct from the DNA molecule of group I. Further, the molecule of group XI is distinct from the molecule of group XII, because they act by different route, i.e. disrupting the direct versus indirect interaction of B1 protein

molecules to which B1 protein binds. In addition, the molecule of group XIII is distinct from the molecules of groups XI and XII, because disrupting the direct or indirect interaction of B1 protein molecules to which B1 protein binds does not necessarily mean that the protein kinase activity of B1 is interfered.

Groups IV-IX, XIV-XX are additional methods, which are distinct from the method of group I, and from each other, because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species B1 proteins and isoforms, analogs or derivatives thereof are distinct because they are structurally distinct.

The species inflammation is distinct from cell death pathways or other signaling pathways, because they involve different conditions.

The species extracellular application is distinct from the species intracellular application, because they have different method steps.

The species Caard, kinase or intermediate domains are distinct because they are structurally distinct.

The species preventing a pathological condition is distinct from the species treating a pathological condition, because treating a pathological condition does not necessarily mean that said pathological condition is prevented.

The species whole length B1, carboxy terminal portion of B1, or N-terminal portion of B1 are distinct because they are structurally distinct.

.Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

March 22, 2001

SUSAN UNGAR, PH.D
PRIMARY EXAMINER